Instruction manual

Refraction unit bon E-50

GA bon E-50 Rev 1.0 E 211005.doc

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Appendix: EC Declaration of Conformity

1 Introduction

Dear customer

Thank you for purchasing our bon E-50 refraction unit. Please read the operating instructions carefully before using the device. Keep these instruction manual safe for future use.
Please observe the safety instructions.
If you have any further questions, please contact our customer helpline.

Meaning of the symbols in the operating instructions

Caution! Please observe safety instructions with this symbol to prevent personal danger or damage to property.

Important! Indicates particularly important information to maintain the function of the device/system or to extend its life.

Note! Indicates information for correct use so that errors may be avoided.

This publication may not be copied or transferred without prior agreement from bon Optic.
bon Optic reserves the right to make changes in the interest of technical development. These operating instructions are not subject to updating.

2 Important information

2.1 System information

Name of device : bon E-50

Manufacturer : bon
Optic Vertriebsgesellschaft mbH
Stellmacherstraße 14
D- 23556 Lübeck

2.2 Application and classification

2.2.1 Application (appropriate use)

The bon E-50 refraction unit is used for holding ophthalmologic apparatus such as slit lamps and ophthalmometers. These instruments can be positioned in front of the patient for the purposes of an examination.

2.2.2 Classification

The bon E-50 refraction unit is a Class 1 non-invasive, active medical device in accordance with the classification regulations of Directive 93/42/EWG on medical devices (MDD).

2.3 Liability

The refraction unit is manufactured according to the current technical status and the recognised safety regulations and is tested in accordance with strict quality criteria.
bon Optic only accepts liability for the safety, reliability and performance of the device if

- any changes or repairs have been carried out by a person authorised by bon Optic to do so.
- the power supply to which the device is connected corresponds to DIN VDE 0100-710.
- the device is operated in accordance with these operating instructions.
- the operator complies to the Ordinance on the Operation of Medical Devices (MPBetreibV).

If the system is assembled, changed or repaired by an unauthorised person, if it is improperly maintained or not used as described in 2.2.1, the manufacturer is no longer liable.

2.4 Scope of delivery

1 x refraction unit bon E-50 as per version ordered

2 x plugs for table apparatus (only for version with adjustable table)

1 x 1.5 m power cable

1 x instruction manual

Fuse kit with:

2 x	T 3.15 A	(for fuses F1, F4)
2 x	T 5.0 A	(for fuses SF5, F6)
1 x	T 4.0 A	(for fuse F2)
1 x	T 6.3 A	(for fuse F3)

3 Safety instructions

Please follow the legal requirements on accident prevention and observe the following safety instructions!

Setting-up and installation:

- The refraction unit should not be assembled and operated in damp rooms.
- Ensure that the device is on a level and stable surface during assembly.
- Do not use the openings of the unit as carry handles! Hold the unit only by its base!
- The mains voltage must be the same as stated on the product label.
- The maximum load-bearing capacity of the adjustable table (2) is 40kg, or max. 25kg when it is in position 1.

Operation:

- Do not subject the device to any extremes of temperature. It is recommended that the product be used at temperatures of between +10° C and +40°C.
- Avoid dropping or splashing water on the device
- The maximum load-bearing capacity of the patient's chair (3) is 170kg and should not be exceeded.
- The lifting column of the patient's chair is not designed for extended use. After being used for 60 seconds, the lifting column must be left to cool for 9 minutes.
- Ensure that the adjustable table (2) does not collide with the patient's legs when the patient's chair (3) is being moved upwards.
- Do not sit on the moveable table (2). Avoid placing unnecessary weight on it, such as leaning on it.
- Do not place your hands into the openings of the refraction unit. They could be injured or crushed!

Other information:

- Do not pull on the cable in order to remove the plug from the power point.
- Ensure that the cable cannot be stepped on or tripped over. Ensure that no other damage occurs to the cable (e.g. sharp edges, high heat)
- Disconnect the apparatus from the mains during repair and maintenance.

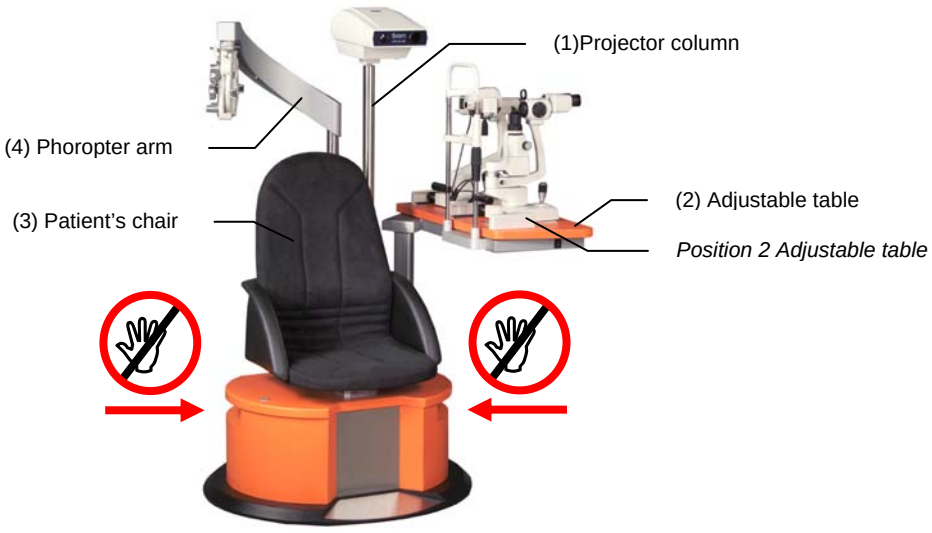


Fig. 3-1: Refraction unit bon E-50

4 Setting-up, assembly, repair

Expert staff from bon Optic or your distributor will set up and assemble the refraction unit.

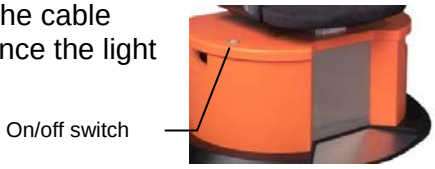
Changes or repairs to the refraction unit may only be carried out by persons authorised by bon Optic. Medical devices that are linked to the electricity supply of the refraction unit must be shown to comply with DIN EN / IEC specifications. All configurations must meet the requirements of the DIN EN 60601-1-1 (IEC 601-1) standard. Non-electrical devices that are connected to the unit must not affect the safety level of the unit. Changes to the refraction unit must not endanger patients, users and the surroundings.

Repairs that can be carried out without a technician can be found in Chapter 6: Maintenance and care

5 Service

5.1 Powering-up

Connect the refraction unit to the appropriate socket using the cable provided and turn it on. The refraction unit is ready to use once the light comes on.



5.2 Description and operation of the components

You will have the following components depending on the version of your refraction unit:

5.2.1 Adjustable table

Pull the adjustable table around the refraction unit in order to move it from the stand-by to the operating position. When it is in place, the adjustable table will sit firmly in a stable position.

The adjustable table is used for holding ophthalmologic devices such as slit lamps and ophthalmometers. These devices can be moved with the adjustable table into operating positions 1 and 2. Use the table lock (2) for this.

Fig. 5-1: Operating position 1

Fig. 5-2: Operating position 2

When moving between operating positions 1 and 2 the supply voltage is automatically connected for the appropriate table device. The adjustable table has a potentiometer (1) for continuous adjustment of the supply voltage (e.g. for the brightness of the slit lamp).

Electricity supply for the table devices

Table devices are supplied with electricity via the connection sockets in the adjustable table. Please contact the expert staff at bon Optic for configuration of/changes to the electricity supply. **Further details on electricity supply can be found in Chapter 8: Technical data.**

5.2.2 Patient's chair

The height of the patient's chair (up and down movement) can be adjusted by the chair button on the adjustable table.

5.2.3 Phoropter arm

Pull the phoropter arm around the refraction unit in order to move it from the stand-by to the operating position. When it is in place, the phoropter arm will sit firmly in a stable position.

The phoropter arm is to be used only for phoropters. Do not hang any other objects on it!

You can change the height and angle of the phoropter arm using the adjustable screws.

5.2.4 Projector column

The projector column is used for chart projectors. Attach the apparatus by using the aforementioned power cable. By using the adjustable screws you can vary the height of the column by approx. 10cm.

6 Maintenance and care

6.1 Care

Clean the refraction unit with a clean, damp cloth. Do not use any abrasive or harsh cleaning products!

6.2 Maintenance and safety checks

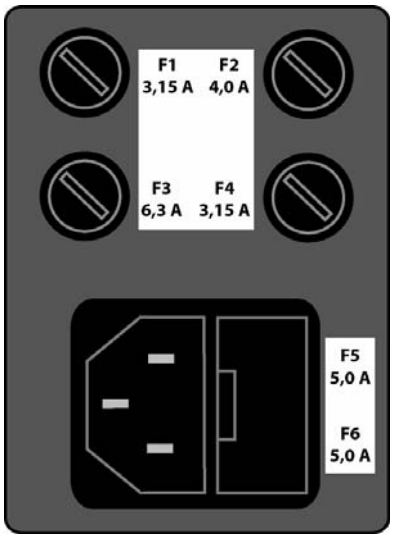
When used properly, the refraction unit should not require repeated maintenance. For repairs or technical problems please contact the bon Optic customer services department.
For this device, no special safety checks are required. In order to meet the requirements of the directive on the operation of medical devices, we recommend regular testing of the electrics in accordance with DIN VDE 0751 in connection with the electricity supply.

6.3 Repairs you can carry out yourself

6.3.1 Changing the fuses

Use only type (T) fuses with the fuse values shown in Table 1!

1) Disconnect the refraction unit from the mains before changing a fuse!
2) Open the appropriate fuse element with a screwdriver.
3) Remove the old fuse from the holder and insert a new fuse of the same type.
4) Place the fuse holder back into the fuse socket.
5) Close the fuse element with the screwdriver.



Component	Fuse	Fuse value/A
Chair unit	**F1**	3.15
Adjustable table (examination apparatus)	**F2**	4.0
Adjustable table (examination apparatus)	**F3**	6.3
*back-up supply 12 V	**F4**	3.15
Main fuse mains connections	**F5**	5.0
Main fuse mains connections	**F6**	5.0

Table 1: Fuses for the refraction unit

7 Guarantee and disposal

Should defects as the result of material or production errors occur within 24 months of purchase, we guarantee free-of-charge repair of the refraction unit or we will decide whether to offer you a free exchange, provided that:

- A receipt with the date of purchase can be provided.
- The device has been used properly and in accordance with the conditions of use.
- Repairs have not been carried out by anyone other than the bon Optic customer service team or persons authorised by bon Optic.

Guarantee services do not result in extension of the guarantee, nor do they represent the start of a new guarantee. The sales guarantee is not applicable to second-hand products.

The terms and conditions of trade of bon Optic also apply.

Disposal

This refraction unit contains components that should not be disposed of in normal household waste. Please inform the waste disposal company or contact bon Optic.

8 Technical data

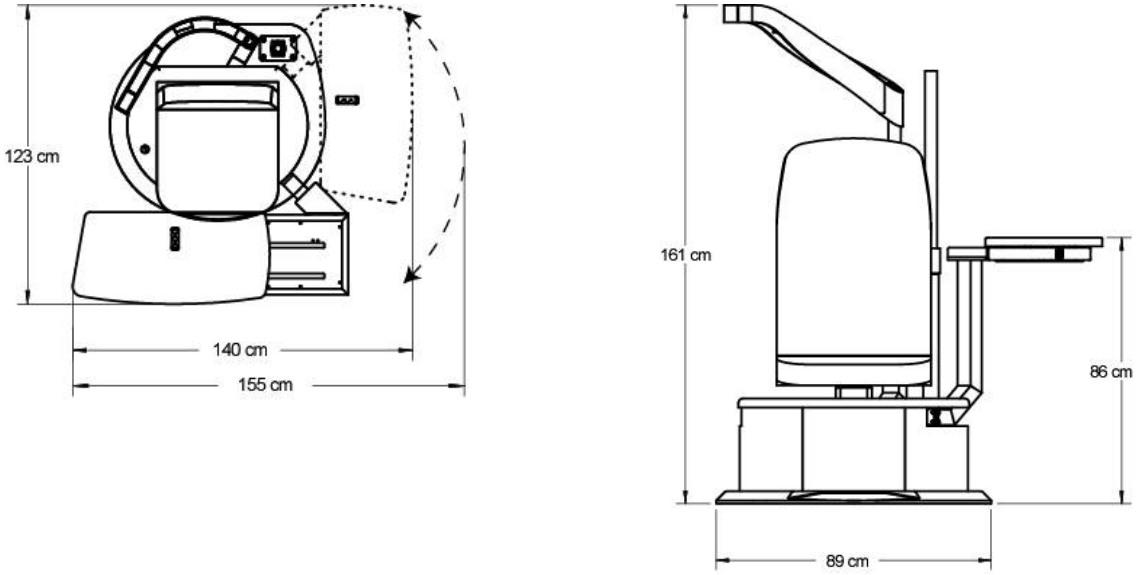


Fig. 8-1: Refraction unit bon E-50 (Plan view and front view)

Further measurements	
Height of projector column	130-140 cm
Height of seat on chair (lowest setting)	41.5 cm
Height of seat on chair (highest setting)	63 cm

Weight	
Maximum weight of equipment without additional apparatus	approx. 150 kg

Electrical date for refraction unit	
Mains voltage	230 V AC
Mains frequency	50 / 60 Hz
Connection power	750 VA
*Output 1 Adjustable table	6 V AC / 12 V AC
*Output 2 Adjustable table	6 V AC / 12 V AC
Max. power output 1 + output 2	88 W
Safety class	I
Apparatus type	B
Safety type	IP 21

Operating conditions refraction unit	
Air temperature	+10° C up to +40° C
Relative humidity	30% to 75%
Air pressure	700 hPa to 1060 hPa

* For changes to the electricity voltage please contact our technical support team.

Lifting column (Chair unit)	
Power supply	230 V / 50 Hz
Consumption	2.2 A
Safety class	I
Max. load on the axis	1800 N (approx.170kg)
Duty ratio (chair column)	S2 10% based on 10 min.
Lift	215 mm
Speed with load	approx. 16 mm/s
Thermal switch	Yes
Limit switch on/off	Yes

Jumper	Connection Tabletop unit 1 (TG1)	Connection Tabletop unit 2 (TG2)
AC1/EIN2	6 V	6 V
AC2/EIN2	12 V	6 V
AC2/EIN2*	12 V	12 V

**Change voltage: Feeder clamp 63 and 64*

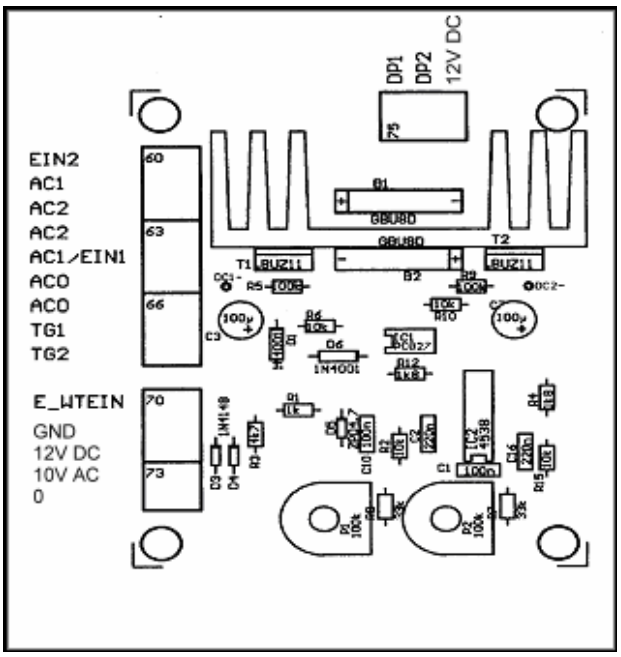


Fig. 8-2: circuit board (power supply)

Feeder clamp	Name	Description
60	EIN2	Connection for jumper
61	AC1	Connection for jumper
62	AC2	Connection for jumper
63	AC2	Voltage for control: 14 V AC
64	AC1/EIN1	Voltage for control: 8,3 V AC
65	AC0	Output voltage for tabletop unit: Ground
66	AC0	Output voltage for tabletop unit: Ground
67	TG1	Output voltage for tabletop unit 1 (6 V AV / 12 V AC)
68	TG2	Output voltage for tabletop unit 2 (6 V AV / 12 V AC)
70	E_WTEIN	Switching voltage: 12 V AC
71	GND	Switching voltage: Ground
72	12 V DC	Switching voltage: 12 V DC
73	10VAC(SB)	Operating voltage: 10 V AC
74	-	Operating voltage: Ground
75	DP1	Potentiometer adjustable table
76	DP2	Potentiometer adjustable table
77	12V DC	Voltage 12 V DC

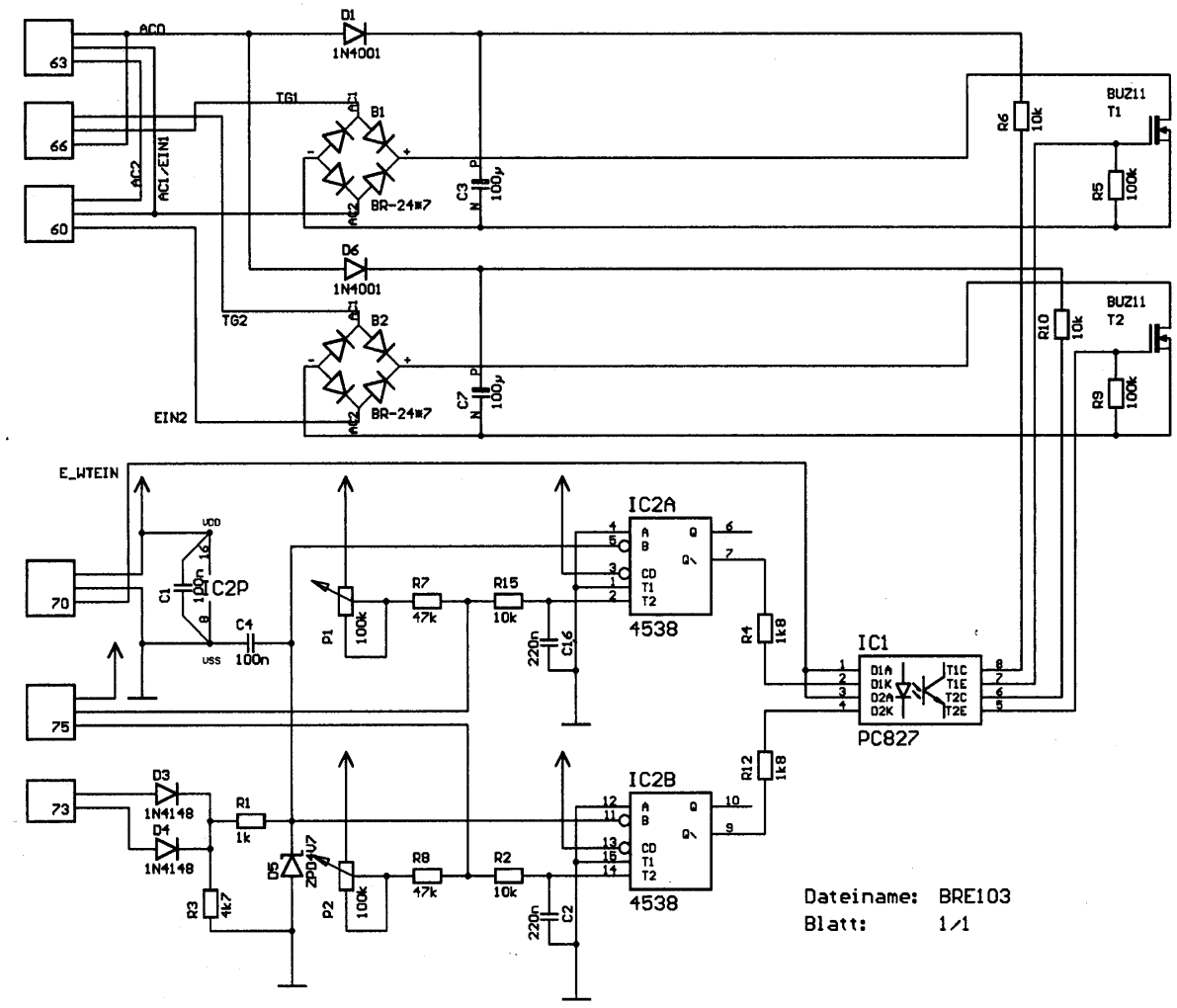


Fig. 8-3: Circuit diagram

Should EMC disruptions (**e**lectro-**m**agnetic **c**ompatibility) occur, please contact bon Optic customer support.

Label Symbols	
	Fuse
	Read instruction manual
	Application part type B

Transport requirements	
	Temperature: -5 °C to +45 °C (+23 °F to +113 °F)
	Air pressure: 650 hPa to 1100 hPa
	Relative humidity: 25% to 80%
Maximum conditions – no longer than 60 days in a row	

EU - KONFORMITÄTSERKLÄRUNG
EC – DECLARATION OF CONFORMITY

Hersteller-Adresse: (Manufacturer's address)	bon Optic Vertriebsgesellschaft mbH Stellmacherstraße 14 D-23556 Lübeck
Gerätetyp / UMDNS-CODE: (Device type/ UMDNS-CODE)	Untersuchungs-/Behandlungsplatz (18-014) Examination/treatment (18-014)
Gerätebezeichnung: (Device name)	**Refraktionseinheit bon E-50** **Refraction unit bon E-50**
Klassifizierung: (Classification)	**1** (Richtlinie 93/42/EWG, Anhang IX, Regel 1) **1** (MDD 93/42/EEC, appendix IX, rule 1)

Wir erklären hiermit die Übereinstimmung des vorgenannten Produkts mit der EU-Richtlinie 93/42/EWG über Medizinprodukte.

We declare the compliance of the device with the requirements of Directive 93/42/EEC on medical devices.

Angewandete Normen: (Applicable standards)	DIN EN 60601-1 DIN EN 60601-1-2 EN 1441	(03/96) (09/94) (10/97)
Überwachungsbehörde/ ID-Nr.: (Notified body/ Identification number)	**TÜV Berlin / 0197**	

Das Gerät ist gekennzeichnet mit / The device is marked with CE

Lübeck, 24 October 2005

(H. Jochen Kaber, managing director)